K133666

FEB - 5 2014

5 510(k) Summary

Fisher & Paykel HEALTHCARE

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Contact person/submitter	Elizabeth Goldstein
Date prepared	27 November 2013
Contact details	Address: 15 Maurice Paykel Place Paykel Building East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100 Fax: +64 9 574 0148
Trade name	RT016 Inspiratory Filter
Common name	Breathing circuit bacterial filter
Classification name	Breathing circuit bacterial filter Class II (21 CFR §868.5260) Product code CAH (Filter, Bacterial, Breathing-Circuit)
Predicate device	RT019 Inspiratory/Expiratory Filter (K050927)

5.1 Device Description

The Fisher & Paykel Healthcare RT016 Inspiratory Filter is intended for use between a ventilator and breathing circuit. Its function is to remove microbiological and particulate matter from gases entering a breathing circuit. The RT016 is intended to be connected to the ventilator inspiratory port. It is not directional in terms of flow and is a single use device.

The filter is comprised of a female (22 mm) filter housing, filter media and male (22 mm) filter housing. The filter media is a depth-type, electrostatic, hydrophobic media which traps microbiological and particulate matter. The filter media is held in place between the female and male filter housings. Both the female and male filter housings have standard 22 mm diameter connectors which have been designed to comply with ISO 5356-1.

5.2 Indications for Use

The Fisher & Paykel Healthcare RT016 Inspiratory Filter is intended for use between a ventilator and breathing circuit. Its function is to remove microbiological and particulate matter from gases entering a breathing circuit. The RT016 is intended to be connected to the ventilator inspiratory port. It is not directional in terms of flow and is a single use device.

5.2.1 Indications for Use Comparison

The indications for Use Statements of the subject device, RT016 Inspiratory Filter, and the predicate device, RT019 Inspiratory/Expiratory Filter (K050927), are identical with the exception of the following:

- The placement of the filter with a ventilator system, where:
  - The subject device, RT016 Inspiratory Filter, is intended to be connected to the ventilator inspiratory port only.
  - The predicate device, RT019 Inspiratory/Expiratory Filter (K050927), may be connected to the ventilator inspiratory and/or the ventilator expiratory port.

This change in configuration does not raise any new questions of safety or effectiveness for the following reasons:

- The placement of the RT016 Inspiratory Filter on the ventilator inspiratory port is also an approved configuration for the predicate device.
- The RT016 Inspiratory Filter labelling clearly identifies the device as an *inspiratory* filter and shows the RT016 Inspiratory Filter connected to the ventilator inspiratory port.

Refer to Table 5.1 on the following page for a side-by-side comparison of the Indications for Use Statements of the subject and predicate devices.

Design/technological characteristic for comparison	Subject device (RT016 Inspiratory Filter)	Predicate device (RT019 Inspiratory/Expiratory Filter, K050927)	Comments
Indications for use	• The Fisher & Paykel Healthcare RT016 Inspiratory Filter is intended for use between a ventilator and breathing circuit.	• The Fisher & Paykel Healthcare RT019 Inspiratory/Expiratory Filter is intended for use between a ventilator and breathing circuit.	*Identical*
	• Its function is to remove microbiological and particulate matter from gases entering a breathing circuit. The RT016 is intended to be connected to the ventilator inspiratory port.	• Its function is to remove microbiological and particulate matter from gases entering and/or exiting a breathing circuit. The RT019 is intended to be connected to the ventilator inspiratory and/or expiratory ports.	*Identical* The function of the subject device and predicate device is *identical*. However the subject device is intended to be connected to the ventilator inspiratory port only, whereas the predicate device may be connected to the ventilator inspiratory and/or expiratory ports.
	• It is not directional in terms of flow and is a single use device.	• It is not directional in terms of flow and is a single use device.	*Identical*
	• Availability: prescription use (Part 21 CFR 801 Subpart D)	• Availability: prescription use (Part 21 CFR 801 Subpart D)	*Identical*

Table 5.1 A comparison of the Indications for Use of the subject and predicate devices

5.3 Technological Characteristics Comparison

The subject device, RT016 Inspiratory Filter, is *identical* to the predicate device, RT019 Inspiratory/Expiratory Filter (K050927), with respect to the following technological characteristics:

- Function, i.e. to remove microbiological and particulate matter from gases, as per the Indications for Use.
- Reusability (i.e. single use) and sterility (i.e. non-sterile).
- Design:
  - All components of the RT016 Inspiratory Filter are *identical* to the corresponding components of the RT019 Inspiratory Expiratory Filter, including materials and processing;
- Performance (i.e. filtration efficiency).

The subject device, RT016 Inspiratory Filter, differs from the predicate device, RT019 Inspiratory/Expiratory Filter (K050927), in that:

- The predicate device, RT019 Inspiratory/Expiratory Filter (K050927), has insulation housing to reduce condensation when used on the ventilator expiratory port (i.e. used with gases which are warm and humid), whereas the RT016 Inspiratory Filter does not have an insulation case as it is used on the ventilator inspiratory port only (i.e. on gases which are dry).

Refer to Table 5.2 for a side-by-side comparison of the key technological characteristics of the subject device, RT016 Inspiratory Filter, and the predicate device, RT019 Inspiratory/Expiratory Filter (K050927).

Design/technological characteristic for comparison	**Subject device (RT016 Inspiratory Filter)**	**Predicate device (RT019 Inspiratory/Expiratory Filter, K050927)**	**Comments**
Configuration	• Connected to the ventilator inspiratory port	• Connected to the ventilator inspiratory port	*Identical*
		• Connected to the ventilator expiratory port	As per the Indications for use, the subject device is intended to be connected to the ventilator inspiratory port only.
Reusability	• Single use only	• Single use only	*Identical*
Components	• Female (22 mm) filter housing; • Filter media; • Male (22 mm) filter housing	• Female (22 mm) filter housing; • Filter media; • Male (22 mm) filter housing;	*Identical* All components used in subject device are *identical* to the corresponding components used in the predicate device, including *identical* materials and processing.
		• Male insulation casing; • Female insulation casing	The subject device does not include the male or female insulation casing components.
Connectors	• Standard 22 mm connectors • Designed to comply with ISO 5356-1:2004	• Standard 22 mm connectors • Designed to comply with ISO 5356-1:2004	*Identical*

Design/technological characteristic for comparison	Subject device (RT016 Inspiratory Filter)	Predicate device (RT019 Inspiratory/Expiratory Filter, K050927)	Comments
Sterility	• Supplied in a non-sterile state • Non-sterile when used	• Supplied in a non-sterile state • Non-sterile when used	*Identical*
Filtration efficiency	• Bacterial: >99.9997% • Viral: >99.99% • Salt test: 98.17%	• Bacterial: >99.9997% • Viral: >99.99% • Salt test: 98.17%	*Identical*
Technical specifications	• Resistance to flow: o 0.35 ± .06 cmH_2O at 15 L/min o 0.71 ± 0.12 cmH_2O at 30 L/min • Internal volume (i.e. compressible volume): 38 mL • Compliance: 0.13 mL/cmH_2O • Gas leakage: <5 mL/min at 70 ±3.5 cmH_2O	• Resistance to flow: o 0.35 ± .06 cmH_2O at 15 L/min o 0.71 ± 0.12 cmH_2O at 30 L/min • Internal volume (i.e. compressible volume): 38 mL • Compliance: 0.13 mL/cmH_2O • Gas leakage: <5 mL/min at 70 ±3.5 cmH_2O	*Identical*

Table 5.2 A comparison of the key technological characteristics of the subject and predicate devices

5.4 Non-Clinical Tests

The RT016 Inspiratory Filter and the predicate device, RT019 Inspiratory/Expiratory Filter (K050927), share the same filter media component and therefore the non-clinical tests summarized below are applicable to both devices.

The following performance characteristics of the filter media were tested:

- Bacterial filtration efficiency;
- Viral filtration efficiency; and
- Filtration efficiency as per the salt test method specified in BS EN ISO 23328-1:2008.

The results of the performance testing are as follows:

- Bacterial filtration efficiency: >99.9997%;
- Viral filtration efficiency: >99.99%; and
- Filtration efficiency as per the salt test method (NaCl): 98.17%.

The filtration of the two devices shows that the filtration performance is *identical.*

5.5 Clinical Tests

Not applicable – no clinical testing was performed with respect to the RT016 Inspiratory Filter.

5.6 Conclusion

The comparison of the technological characteristics summarized above demonstrates that the subject device, RT016 Inspiratory Filter, is substantially equivalent to the predicate device, RT019 Inspiratory/Expiratory Filter (K050927). In addition, bench testing, as summarized above, supports both performance of the RT016 Inspiratory Filter in accordance with its intended use as well as substantial equivalence of the RT016 Inspiratory Filter to the RT019 Inspiratory/Expiratory Filter (K050927).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 5, 2014

Fisher & Paykel Healthcare
Elizabeth Goldstein
Regulatory Affairs Specialist
15 Maurice Paykel Place
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Auckland, New Zealand 14 348

Re: K133666
Trade/Device Name: RT016 Inspiratory Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: November 27, 2013
Received: November 29, 2013

Dear Ms. Goldstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

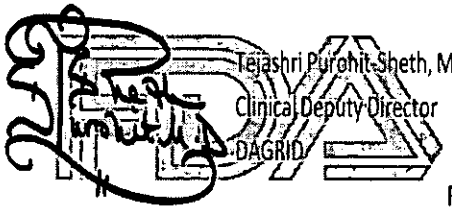
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin Keith
Acting Division Director
Division of General Hospital, Respiratory,
Anesthesiology Infectious Control, and Dental
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133666

Device Name
RT016 Inspiratory Filter

Indications for Use *(Describe)*

The Fisher & Paykel Healthcare RT016 Inspiratory Filter is intended for use between a ventilator and breathing circuit. Its function is to remove microbiological and particulate matter from gases entering a breathing circuit. The RT016 is intended to be connected to the ventilator inspiratory port. It is not directional in terms of flow and is a single use device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Anya C. Harry -S
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